



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 23, 2016

Cynosure, Inc.
Ms. Connie Hoy
Vice President of Regulatory Affairs
5 Carlisle Road
Westford, Massachusetts, 01886

Re: K133364

Trade/Device Name: Picosure™ Workstation

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: June 15, 2014

Received: June 17, 2014

Dear Ms. Hoy:

This letter corrects our substantially equivalent letter of July 22, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Jennifer R.
Stevenson -A**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 5
510(K) Summary
PicoSure™ workstation

This 510(K) Summary of safety and effectiveness for the PicoSure™ workstation is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cynosure, Inc.
Address:	5 Carlisle Road Westford, MA 01886 USA
Contact Person:	Connie Hoy, SVP of Regulatory Affairs
Telephone:	1-781-993-2414
Email:	choy@cynosure.com
Preparation Date:	April 4, 2016
Device Trade Name:	PicoSure™ workstation
Common Name:	Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Device(s):	PicoSure™ workstation (K)121346 Hoya ConBio RevLite (K)103118
Description of the PicoSure™ Workstation:	The PicoSure™ workstation is a high-powered, Q-switched Alexandrite system that delivers laser energy in the 755-nm wavelength. The system consists of a console that houses the power supply, control electronics and the laser. Laser energy is delivered to the skin via an articulated arm. The laser is activated using a footswitch.
Intended use of the PicoSure™ Workstation	The PicoSure™ workstation is indicated for tattoo and benign pigmented lesion removal. The PicoSure™ workstation operating with the 3mm or 6mm handpiece and the FOCUS lens array is indicated for the treatment of acne scars in Fitzpatrick skin types I-IV.
Performance Data:	IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance Steam Sterilization Test Report 673257 Software Verification and Validation Testing Report 860-7012-SRV

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Results of Clinical Study:

Two clinical studies were conducted.

One study assessed facial acne scars. In 17 patients who completed the study, a total of 46 acne scars underwent a mean of 6.3 treatments with either the 3mm or 6mm handpiece, each operated with the FOCUS lens array. Before and after photographs were evaluated by three blinded evaluators, who were able to identify correctly the before and after images in 70% of the 17 subjects. The mean improvement score (scale 0-3) was 1.9. The non-blinded treating physician reported a 100% overall satisfaction rate, scoring the improvement in 47% of subjects as "satisfied" and 53% as "extremely satisfied." Subjects reported a satisfaction rate of 87% (53% "satisfied" and 27% "extremely satisfied").

A second study was conducted on normal skin on the arm of 2 subjects and the leg of a 3rd subject to evaluate the tissue response to treatment of the FOCUS lens array. Three patients were treated with the 6mm lens with FOCUS array at 0.71J/cm² and with the 3mm lens with FOCUS array at 2.83J/cm². Biopsies were performed in untreated skin and in treated skin immediately post treatment, 7 days post treatment and 15 days post treatment. Treatment induced immediate focal epidermal vacuolization and small foci of degenerated keratinocytes. At days 7 and 15, skin exhibited intact epidermis with mild, superficial dermal lymphocytic infiltrates in peri-vascular pattern.

Technical Comparison:

Specifications

	PicoSure™ Workstation (current submission)	PicoSure™ Workstation (previously cleared)	RevLite
Laser Type	Flashlamp excited Q-switched alexandrite	Flashlamp excited Q-switched alexandrite	Flashlamp excited Q-switched Nd:YAG
Wavelength	755nm	755nm	532 nm, 585 nm 650 nm, & 1064 nm
Energy per pulse	0.2 J/cm ²	0.2 J/cm ²	0.85 J/cm ²
Maximum Average Fluence	6.37 J/cm ²	6.37 J/cm ²	12 J/cm ² (1064nm) 5 J/cm ² (532nm) 10 J/cm ² (585nm) 6 J/cm ² (650 nm) 1.2 J/cm ² (532Lite)
Repetition Rate	Single pulse, or 1, 2.5, 5, or 10 pulse(s) per second (Hz)	Single pulse, or 1, 2.5, or 10 pulse(s) per second (Hz)	Single & double pulse, 1, 2, 5, & 10 Hz pulses per second
Pulse Width	450ps-900ps	450ps-900ps	5-20 ns
Spot Sizes	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm With FOCUS lens array: 3mm,6mm	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm	Fixed 2 – 8 mm (varies by wavelength)

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Conclusion:

The PicoSure Workstation is substantially equivalent to other existing laser systems in commercial distribution for use in Dermatology and Plastic Surgery.

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